State of New Hampshire
ADVERSE EVENT REPORTING
2013REPORT

Prepared by
New Hampshire Department of Health and Human Services
Office of Operations Support
Bureau of Licensing & Certification

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Adverse Event Report 2013-Hospitals & Ambulatory Surgery Centers

In accordance with New Hampshire's Adverse Event Reporting System RSA "The Commissioner shall" … Section IV (d) Publish an annual report describing, by facility, adverse events reported, outlining, in aggregate, corrective action plans and the findings of root cause analyses and making recommendations for legislation relative to state health care operations.

Executive Summary:

The Institute of Medicine (IOM) published in 1999 the first in a series of papers titled To Err is Human: Building a Safer Health Care System. One step towards reducing adverse events is to develop a nationwide mandatory adverse event reporting system. To date no such nationwide system exists. New Hampshire joined a growing list of States that require mandated reporting of 29 Adverse Events or "Never Events" developed by the National Quality Foundation (See Appendix A for the list of adverse events.); adverse event reporting became law in New Hampshire effective January 1, 2010.
The purpose of reporting of these events is to balance quality improvement accountability, not to punish hospitals, ambulatory surgery centers or the dedicated practitioners that provide the care.

The law requires that adverse events be reported in a format that lists hospitals or ambulatory surgery centers related to the event (See Table 1). Release of the fourth annual summary of events data reported under New Hampshire's Adverse Events Reporting System law, RSA Section 151:37 - 40, finds that 18 of 29 licensed hospitals reported adverse events. 1 Ambulatory Surgery Center reported an adverse event.

On 7/15/2013, the legislation updated Section 151:39 V. to "The commissioner shall monitor with the National Quality Forum of amendments to the forum's list of reportable events and shall report to the general court whenever the list needs to be modified."

It is also important to note that no consumer complaints were received by the Department concerning the 51 adverse events reported. Complaints and adverse events are handled by Health Facilities Administration-Certification (HFA-C) as two distinct actions. The Department is responsible for the health, safety and well-being of New Hampshire's citizens. HFA-C carries out vital quality assurance, patient safety and regulatory in support of Department's goal.

RSA 15 1 :40 establishes that failure of a facility to report timely, adverse events to include root cause analysis and plans of correction, be subject to disciplinary actions. During calendar year (CY) 2013 no actions were required for late reporting.

In order to answer the question, "How do you know the reporting facility did what they said they were going to do to correct the problem?" HFA-C sampled over 10% of the adverse events and asked for and received specific performance data to be submitted as a follow up to their CAP. All sampled facilities sampled provided performance information. It was concluded that the hospitals we followed through with actions to correct the problems.

Technical Aspects of Reporting-The law requires that a hospital or ambulatory surgery center must report any adverse health care event "as soon as reasonably and practically possible, but no later than 15 working days after the discovery of the event". The Initial Reporting Form (Appendix B) is submitted to HFA-C via E-mail, US Mail or other methods.

Once the Initial Report is received the form is checked for completeness and an acknowledgement is sent to the contact person listed on the form indicating that the Department has received the report. This same procedure is used for the Root Cause Analysis and Corrective Action Plans. The RCA and CAP are due within 60 days of discovery. HFA-C determines if all documents are complete and accurate, and if plans submitted are based on current standards (See Appendix C & D for the internal evaluation tools used.)

Acknowledgements:

The Department's Adverse Event Reporting Staff would also like to thank the many staff at New Hampshire's hospitals for their prompt reporting of events and reporting of root cause analysis and corrective action plans. Of note was the fast response by facilities for additional data concerning quality progress metrics. Questions concerning this report may be directed to:
michael.e.fleming@dhhs.state.nh.us

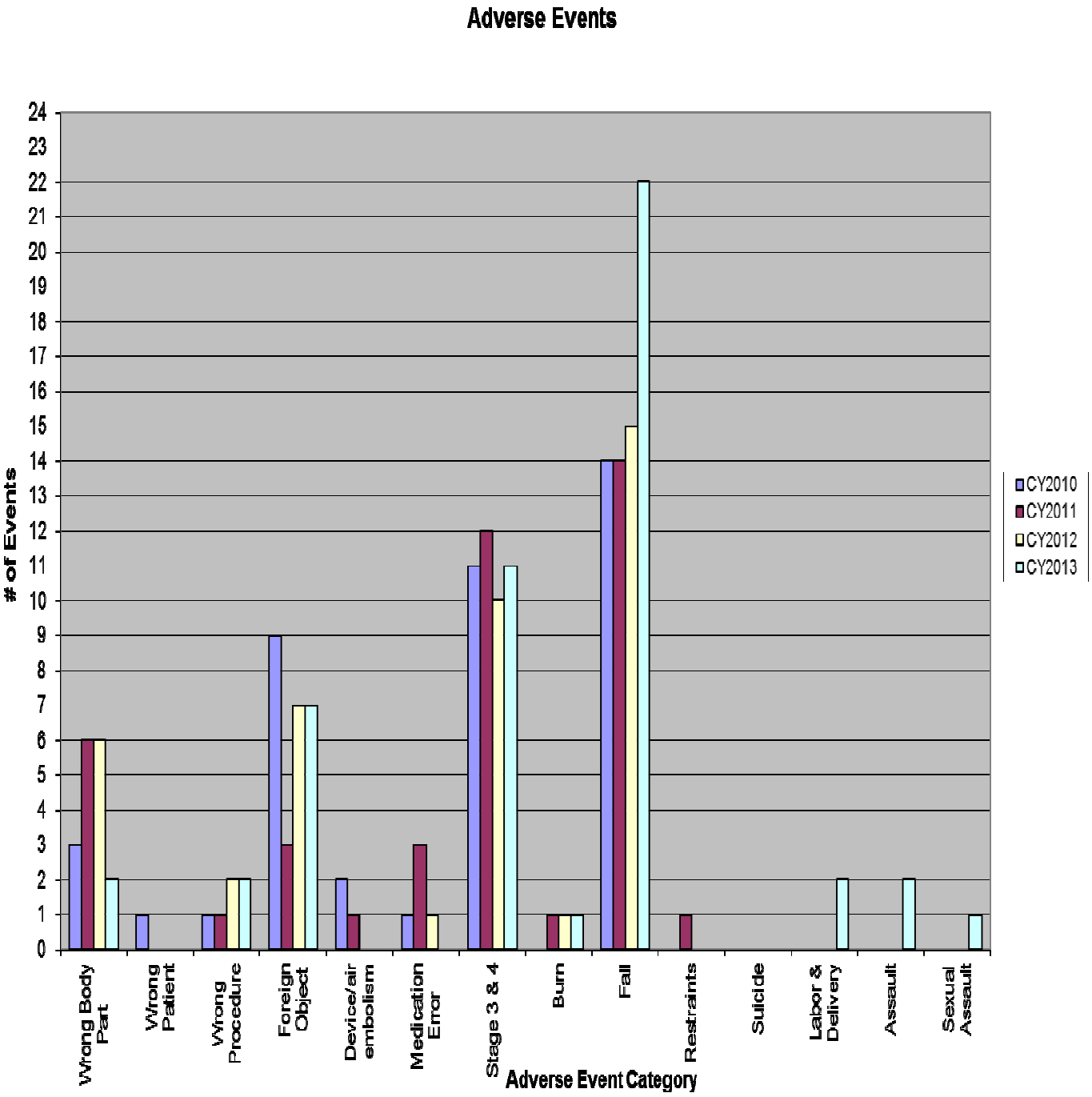
Recommendations:

The department will be working with the New Hampshire Hospital Association with the following recommendations: Numbers of surgeries each hospitals/ACS per year, types of surgeries (cardiac vs orthopedic), number of admissions per year, number of births per year, and number of high risk for falls identified on admission vs not identified as high risk. With this extra data it will help demonstrate or correlate between the hospital(s) and what the data outlook actually compares them with.

List of hospitals that reported an adverse event-Table 1

CY2013		Surgical Event	Surgical Event	Surgical event	Care event	Care event	Care Event	Environmental Event	Pot. Criminal Event	Pot. Criminal Event	
Provider Name	#of Beds	Wrong Body Part	Wrong Procedure	Foreign Object	Labor & Delivery	Stage 3 & 4& unstageable	Fall	Burn	Physical Assault	Sexual Assault	Total reported
Alice Peck Day	25		1	1	1						3
Catholic Medical Center	330			1		2	3				6
Cheshire Medical Center	169			1	1		2				4
Concord Hospital	295			1			2				3
Cottage Hospital	25						1				1
Elliot Hospital	296						4		2		6
Exeter Hospital	100			1			1				2
Frisbie Hospital	112					2					2
Huggins Hospital	25					1					1
Lakes Region Gen Hospital	137					1					1
Mary Hitchcock Mem Hospital	396	1	1			5	4	1			12
Memorial Hospital	25						1				1
Parkland Hospital	86			1							1
Portsmouth Reg Hospital	209						2				2
Southern NH Med Center	188			1			1				2
St. Joseph Hospital	208						1				1
Valley Regional Hospital	25						1				1
Wentworth Douglas Hospital	178									1	1
Bedford Ambulatory Surgical Center		1									1
Total		2	2	7	2	11	23	1	2	1	51

Chart 1- Sum of events reported by type:



Review of the adverse event data in the Chart 1 (above) reveals that 4 categories of events emerge as clusters: Surgical events, Care Management events, Environmental events, and Potential Criminal events. (See Appendix A and Appendix B for category list.)

The Joint Commission describes a Root Cause Analysis as a "process for identifying the basic or casual factors that underlie the variation in performance. A root cause is the most fundamental reason a problem-a situation where performances does not meet expectations-has occurred."

Most of the adverse events reported did not give a single root cause but demonstrate a convergence of multiple contributing factors. Examples of some of these factors reported were:
Assessment: Adequacy, timing, assessment, patient observation, care decision,
Care Planning, Planning and/or collaboration
Communication: oral, written, electronic, on coming staff, with physicians, with family and patients,
Human factors: staffing levels, staffing skills, in-service orientation, competing assessment, other (e.g. rushing, fatigue, distraction, complacency)
Leadership: inadequate policies & procedures, noncompliance with policies and procedures.
Patient Rights: informed consent

Key aggregate findings concerning Root Cause Analysis (RCA) and Corrective Action Plans (CAP) for surgical events:

During CY 2013 there were 11 surgical events. RSA 157:37 IV defines surgery as follows: "Surgery means the treatment of disease, injury, or deformity by manual or operative methods. Surgery includes endoscopies and other invasive procedures."

RCA:

- The "Time Out" process that takes place immediately before a procedure begins and involves the entire surgical team (any member of the team can stop the procedure if any member is in doubt about the surgery) was not consistently adhered to, or there was a lack of ownership by the entire team for the Time Out process.
- Equipment to delicate for procedure.
- Wrong box checked off on consent form.
- Lack of standardized tools for communicating events/reminders during procedures to the entire OR Team.
- OR count sheets did not account for items, like broken or separated device components that become retained foreign objects.
- Informed consent form not completed or specific enough amount of time between office visit and surgery.
- X-ray not sent to OR.
- Lack of visual cues.
- Failed to confirm the correct object/Exit room to get object.
- History & physical not updated.

CAP:

- Policy on Time-Out process revised. All physicians and team members educated on revised policies.
- Mandatory "stand down".

- Use the paper chart vs. electronic chart.
- Change count policy and procedures. Include sheaths and other pieces of surgical supplies on count list. If count is not accurate take action, use radiographic imaging when appropriate.
- Education.
- Checklists.
- Inspect equipment.
- Revise policy and procedures.
- Annual competencies.
- Obtain X-rays.

Key aggregate findings concerning Root Cause Analysis (RCA) and Corrective Action Plans (CAP) for fall:

Falls is still the highest incidents that is reported. Falls remain a leading cause of injury and death in communities, hospitals and in long-term care facilities. Risk for falls include patients who are elderly and/or patients with gait or balance problems or have bowel and bladder incontinence issues. Added risks are the use of multiple medications and patients with cognitive impairment.

During this reporting period 23 falls were reported, ages ranged from 44 yrs. to 94 yrs. The most common fractures were the hip-8, displaced humeral fracture-2, pelvis-1, ankle-1. And two falls that led to a head injury (subdural hematoma). The most common location for falls was out-of-bed-(7), from chair-(4), ambulating with assistance-(3), and between bed and bathroom-(4).

RCA: Factors that contributed to the falls were:

- Bed alarms in use were not set properly or did not sound because it was turned off.
- Lack of hand off communication between units when the patient was transferred.
- Not implementing falls care plan.
- Nursing documentation did not include a review of patient safety issues or interventions to be used.
- Not identified as needing 2 assist in care plan.
- EHR that documents by exception and does not capture a care plan activities that require frequent "rounding" or toileting of patients.
- Gait belt not utilized.
- Several falls were not witnessed with some patient's reporting (after the fall) dizziness before falling.
- No preceptor with new LNA.
- Inconsistent documentation.

CAP: Plans consisted of:

- Establishing and/or clarifying existing fall risk assessments.
- Patient’s status and risks are clearly communicated during handoff or at shift changes or when transferred to a different unit.
- Staggered staffing.
- Frequent toileting.
- Document assessment and transfer techniques and or tools utilized.

- Divisional activities.
- Education.

Key aggregate findings concerning Root Cause Analysis (RCA) and Corrective Action Plans (CAP) for Care Management Events-Pressure Ulcers:

Pressure ulcers also known as bedsores occur when a patient' skin tissue is compressed between a bony prominence and an external surface; such as being in one position for a long period of time. Friction and/or shear force also can contribute to pressure sores.

The underlying health of a patient's soft tissue affects how much pressure, or shear force it takes to damage skin. Examples of risk factors are immobility and co-morbid conditions such as end-stage disease, thyroid disease, and diabetes; drugs such as steroids; impaired blood flow. Other factors are such as excess moisture, and tissue exposure to urine and feces can increase risk.

The severity of pressure sores are categorized by staging:

Stage 1: Intact, redden skin.
Stage 2: Partial thickness skin tissue, presenting as a shallow ulcer or blister.
Stage 3: Full thickness of skin tissue loss.
Stage 4: Full thickness of skin tissue loss with exposed muscle tendon or bone.
Unstageable-Full thickness skin loss, covered with slough or scabbing so that the stage cannot be determined.

During CY 2013 report the hospitals reported pressure ulcers between the following areas: on the, heels, foot, and knee with the majority being on the buttocks and/or the coccyx area. According to adverse event reports the typical patient was medically complex and for the most part located in the ICU with life threatening conditions or had long hospital stay due to their co-morbidities.

RCA:

- Delay in ordering Wound Care Consult.
- Inconsistencies in documenting skin assessments.
- Lack of comprehensive skin assessments.
- Lack of easily accessible cognitive aids at bedside for assessments.
- Policy & Procedures not followed, such as skin assessments not documented.
- Lack of consistent documentation.
- Communication.
- Lack of pressure relieving devices used.
- Lack of full implementation of bed algorithm.

CAP:

- Education in staging.
- Enhance Electronic Medical Record.
- Document Admission Assessment.
- Update Policies/Procedures.
- New rounding process.

- Revise bed algorithm.

APPENDIX A – Reportable events are as follows for Jan. 1, 2013-July, 15, 2013:

- **Surgical Events**

    - Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this subparagraph do not include situations requiring prompt action that occur in the course of surgery or situations where urgency precludes obtaining informed consent.
    - Surgery performed on the wrong patient.
    - The wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this subparagraph do not include situations requiring prompt action that occur in the course of surgery or situations where urgency precludes obtaining informed consent.
    - Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
    - Death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

- **Product or device events including:**

    - Patient death. Or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product.
    - Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. "Device" includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
    - Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

- **Patient protection events including:**

    - An infant discharged to the wrong person.
    - Patient death or serious disability associated with patient disappearance, excluding events involving adults who have decision-making capacity.
    - Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

- **Care management events including:**

  - Patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
  - Patient death or serious disability associated with a hemolytic reaction due to the administration of blood or blood products.
  - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
  - Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility.
  - Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
  - Stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission.
  - Patient death or serious disability due to spinal manipulative therapy.
  - Artificial insemination with the wrong donor sperm or wrong egg.

- **Environmental events including:**

  - Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock.
  - Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
  - Patient death or serious disability associated with a bum incurred from any source while being cared for in a facility.
  - Patient death or serious disability associated with a fall while being cared for in a facility.
  - Patient death or serious disability associated with the use or lack of restraints or while being cared for in a facility.

- **Criminal events including:**

  - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
  - Abduction of a patient of any age.
  - Sexual assault on a patient within or on the grounds of a facility.
  - Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Appendix B: Reportable Events as Defined by National Quality Forum: (July 16, 2013 ongoing)

List of SREs

1. SURGICAL OR INVASIVE PROCEDURE EVENTS

1A. Surgery or other invasive procedure performed on the wrong site (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1B. Surgery or other invasive procedure performed on the wrong patient (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1C. Wrong surgical or other invasive procedure performed on a patient (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

2. PRODUCT OR DEVICE EVENTS

2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities

3. PATIENT PROTECTION EVENTS

3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities
3B. Patient death or serious injury associated with patient elopement (disappearance) (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4. CARE MANAGEMENT EVENTS

4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration) (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4B. Patient death or serious injury associated with unsafe administration of blood products (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers

4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy (new)
Applicable in: hospitals, outpatient/office-based surgery centers

4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities

4G. Artificial insemination with the wrong donor sperm or wrong egg (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen (new)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results (new)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5. ENVIRONMENTAL EVENTS

5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

6. RADIOLOGIC EVENTS

6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area (new)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

7. POTENTIAL CRIMINAL EVENTS

7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7B. Abduction of a patient/resident of any age (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting (updated)
Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities